

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NEWPORT NEWS DIVISION**

SOLSYS MEDICAL, LLC,

Plaintiff,

v.

ORGANOGENESIS, INC.,

Defendant.

Case No. 4:18-cv-00030-HCM-RJK

**DEFENDANT’S REPLY TO PLAINTIFF’S OPPOSITION
TO DEFENDANT’S MOTION TO DISMISS THE COMPLAINT**

Solsys’s claim here is unprecedented. Casting caution and the First Amendment aside, Solsys directly attacks a scientific study published in a respected, peer-reviewed, scholarly journal as “false advertising” under the Lanham Act and Virginia Code section 18.2–216. Wholly missing from Solsys’s brief, however, is any authority that permits such an attack. Thus, Solsys’s claim is literally unprecedented — none of the cases Solsys cites permits a competitor/plaintiff to conscript the Lanham Act as a vehicle to quash scientific opinion published in an independent, peer-reviewed journal simply because it contests the research or its results:

- “[T]he article’s contents are not actionable under the Lanham Act.” *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 498 (2d Cir. 2013).
- “Eastman did not sue Appellants for publishing an article in a scientific journal. . . . This lawsuit is not about Dr. Bittner’s scientific paper.” *Eastman Chem. Co. v. Plastipure, Inc.*, 775 F.3d 230, 234 (5th Cir. 2014).
- “Plaintiff has no quarrel with the Study, be it methodology, conclusions, or otherwise.” *Mimedx Grp., Inc. v. Osiris Therapeutics, Inc.*, No. 16 Civ. 3645 (KPF), 2017 WL 3129799, at *7 (S.D.N.Y. July 21, 2017).

- “Barschall’s articles fall decidedly on the noncommercial, fully protected side of the line.” *Gordon & Breach Sci. Pub’lrs S.A. v. Am. Inst. of Physics*, 859 F. Supp. 1521, 1540 (S.D.N.Y. 1994).
- “The Court finds that there is an abundance of case law to support the proposition that a scientific article is protected noncommercial speech despite the potential for erroneous content.” *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 456 (D.N.J. 2009).
- “[P]eer-reviewed medical journal articles and commercially-available medical textbooks merit the highest degree of constitutional protection.” *Genzyme Corp. v. Shire Human Genetic Therapies, Inc.*, 906 F. Supp. 2d 9, 15 (D. Mass. 2012) (citation omitted).
- “[T]he statements in the journal articles here are not actionable.” *Biolase, Inc. v. Fotona Proizvodnja Optoelektronskih Naprav D.D.*, No. SACV 14-0248 AG (ANx), 2014 WL 12579802, at *4 (C.D. Cal. June 4, 2014).¹

Solsys’s unprecedented attack on the Peer-Reviewed Study² is the essence of its Lanham Act and state law false advertising claims — it pervades the complaint and its accusations against the Cover E-Mail, which it concedes includes and incorporates the entire Study. Thus, Solsys’s attack on the Cover E-Mail is simply a derivative, collateral attack on the Study itself because the Cover E-Mail includes the Study.

¹ After Biolase’s complaint was dismissed, Biolase filed an amended complaint that alleged that the peer-reviewed journal was fraudulent, that it was owned and controlled by the defendant, and that the article was not subject to a legitimate peer-review process. Based on these allegations (which are wholly absent in Solsys’s Complaint), the court allowed the amended Lanham Act claim to proceed. *Biolase, Inc. v. Fotona Proizvodnja Optoelektronskih Naprav D. D.*, SACV 14-0248 AG, 2014 WL 12577153 (C.D. Cal. 2014).

Semco, Inc. v. Amcast, Inc., 52 F.3d 108 (6th Cir. 1995) did not involve a peer-reviewed article or scientific study and is, therefore, totally inapposite to the First Amendment issues raised by the motion to dismiss.

² “Comparative Effectiveness of a Bioengineered Living Cellular Construct and Cryopreserved Cadaveric Skin Allograft for the Treatment of Venous Leg Ulcers in a Real-World Setting,” published in the independent, peer-reviewed medical journal, *Advances in Wound Care*, Vol. 7, No. 3 (Dec. 2017) (hereinafter the “Peer-Reviewed Study” or “Study”). *Advances in Wound Care* is an official publication of the Wound Healing Society (“WHS”). The email that distributed the Study is referred to as the “Cover E-Mail.”

The First Amendment stands as a bulwark against the “methods of litigation” that Solsys brings against the Study. The motion to dismiss involves issues of academic freedom and public health, both of which are “special concern[s] of the First Amendment.” *Keyishian v. Bd. of Regents of the Univ. of the State of N.Y.*, 385 U.S. 589, 603 (1967); *see also Arthur v. Offit*, No. 01:09-cv-1398, 2010 WL 883745, at *4 (E.D. Va. Mar. 10, 2010) (when litigation threatens to curtail speech that relates to an issue of public concern, constitutional and common law protections are at their zenith). Solsys’s Complaint is nothing short of a frontal assault against academic opinions and conclusions that are protected by the First Amendment and are strictly non-actionable under the Lanham Act. As a result, the Complaint should be dismissed in its entirety and with prejudice.

ARGUMENT

I. Solsys’s Claims Fail as a Matter of Law Because They Are Foreclosed by the First Amendment and the Sound Reasoning of Cases Such as *ONY* and *Offit*.

Solsys’s brief failed to demonstrate why *ONY*, 720 F.3d 490, and *Offit*, 2010 WL 883745, do not compel dismissal of its Complaint. Indeed, Solsys’s allegations against Organogenesis are virtually indistinguishable from those presented in *ONY*. *ONY* is the leading case in this area of law and one that Solsys gives short shrift. More significantly, Solsys totally ignored and failed to mention *Offit* — a decision where this Court found that questions of medical science are not actionable.³ Those cases are on point with respect to the peer-reviewed journal article and the published conclusions that Solsys attacks in the instant case.

³ *Offit* involved a defamation claim brought by a vaccine opponent against a vaccine proponent and others based on a *Wired* profile of the proponent. The Lanham Act is merely a statutory species of a defamation-type claim where truth or falsity of a statement of fact is the key element. This Court’s conclusion that questions of medical science are not actionable in a defamation case applies with equal force to a Lanham Act analysis.

In *ONY*, the court explained how academic opinions and conclusions are protected by the First Amendment and are non-actionable under the Lanham Act. *ONY*, 720 F.3d at 497-98 (holding scientific conclusions and accurate statements of those conclusions in advertising are protected by the First Amendment).⁴ And in *Offit*, this Court stated: “Plaintiff’s claim . . . threatens to ensnare the Court in [a] thorny and extremely contentious debate over . . . which side of this debate has ‘truth’ on their side. That is hardly the sort of issue that would be subject to verification based upon a core of objective evidence.” *Id.*, 2010 WL 883745, at *6 (internal quotation marks and citation omitted).⁵ Thus, this Court has embraced Judge Easterbrook’s view that disputes such as these “must be settled by the methods of science rather than by the methods of litigation.” *Underwager v. Salter*, 22 F.3d 730, 736 (7th Cir. 1994).

A. *Case Law Firmly Establishes That Solsys Cannot Attack the Peer-Reviewed Study as “False Advertising” In Violation of the Lanham Act or Virginia Law.*

Much of Solsys’s Opposition and most of the factual allegations of its Complaint directly attack the published, peer-reviewed Study as “highly flawed,” arguing that it has “numerous problems” and a “variety of false statements and negative implications.” *See* Opp’n at 3-7; Compl. ¶¶ 23-29, 35-47. Solsys asserts that because Organogenesis forwarded the Study to an audience of medical professionals specializing in wound care who were also potential customers of Apligraf and TheraSkin, the Cover E-Mail magically transmogrified the Study into “clearly

⁴ “We therefore conclude that, to the extent a speaker or author draws conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement, those statements are not grounds for a claim of false advertising under the Lanham Act.” *Id.* at 498.

⁵ Curiously, Solsys’s Opposition brief does not anywhere address *Offit*, the leading case from this court on the issue of when courts should weigh in (or refrain from weighing in) on academic or scientific disputes — even though *Offit* was cited by Organogenesis in its brief in support of the motion to dismiss.

commercial speech.” *See* Opp’n at 9. And, Solsys points to these alleged “flaws” and “problems” with the Study itself as the basis for its claim that the Study and the Cover E-Mail forwarding the Study “contain[] explicitly false statements and statements that are false by implication,” and thus actionable under the Lanham Act. *Id.* at 11.

The essential defect in Solsys’s argument is that the distribution of the Study does not vacate the First Amendment protection afforded to it. The relevant case law makes clear that a mere scientific disagreement does not turn an academic publication into false advertising within the purview of the Lanham Act. Solsys’s disagreement with the data, methods, or conclusions of the Peer-Reviewed Study does not mean that any statement is either literally false or false by implication. Indeed, the opposite is true — scientific opinions subject to the rigor of a peer review process and published in a scholarly journal are protected by the First Amendment and do not give rise to liability under the Lanham Act.

Even the cases cited by Solsys agree that the publication and dissemination of the Peer-Reviewed Study are similarly protected unless there is a *misrepresentation of the results of that study*. *See, e.g., ONY*, 720 F.3d at 498-99; *Bracco Diagnostics*, 627 F. Supp. 2d at 402, 459. It is self-evident that the Cover E-Mail cannot misrepresent the Study if it “includes and incorporates a linked copy” of that Study, as Solsys alleges. *See* Compl. ¶ 31. Indeed, each of the cases upon which Solsys relies in its Opposition consistently underscore why *ONY* and the First Amendment are dispositive and compel dismissal of this lawsuit.

The first case that Solsys cites in an effort to evade *ONY* and the First Amendment is *Eastman Chemical Co. v. PlastiPure, Inc.*, 775 F.3d 230 (5th Cir. 2014). But that case is different in notable ways. First, the plaintiff there did not contest the academic study, unlike Solsys here. Second, the defendant had not distributed the study, but only distributed an

advertisement that significantly distorted the study's conclusions. For example, the district court noted that the defendant's challenged advertising statements were "made without the necessary context presented by a full scientific study, such as a description of the data, the experimental methodology, the potential conflicts of interest, and the differences between raw data and the conclusions drawn by the researcher." *Id.* at 236 (quoting *Eastman Chem. Co. v. PlastiPure, Inc.*, 969 F. Supp. 2d 756, 764 (W.D. Tex. 2013)). Here, in contrast, the full Peer-Reviewed Study was provided with the Cover E-mail. It gave the sophisticated, highly-educated audience of recipients a fair opportunity to read, discuss, and scrutinize the research and conclusions in the Study itself. And, as noted above, Eastman was not challenging the underlying peer-reviewed study in that case — a key difference from Solsys's attacks on the Study here. *Id.* at 234.

Solsys's reliance on *Gordon & Breach Science Publishers S.A. v. American Institute of Physics*, 859 F. Supp. 1521 (S.D.N.Y. 1994) is also misplaced. First, the case predates *ONY* and, therefore, its usefulness is limited to the extent it was overruled by *ONY*. Second, the parties were, ironically, competing publishers of scientific journals, and the defendant journal had published a list of the most "cost effective" journals, with itself near the top and the plaintiff's journal near the bottom. *Id.* at 1523-25. There were no issues concerning new technologies, the therapeutic efficacy of different medical devices, or the appropriate forum in which to debate and address issues of scientific truth.

Solsys cites *Bracco Diagnostics* and *Genzyme* (both of which are also district opinions decided prior to the Second Circuit's ruling in *ONY*) for the broad proposition that references to journal articles in secondary advertising may, in certain circumstances, constitute actionable commercial speech. But these cases are fully in accord with *ONY*, because they only stand for the proposition that a plaintiff might state a claim for secondary dissemination of a scientific study

based on a *misrepresentation* of the results of such a study. *ONY*, 720 F.3d at 498-99; *Bracco Diagnostics*, 627 F. Supp. 2d at 402, 458-59; *Genzyme*, 906 F. Supp. 2d at 16-17. For example Solsys ignores the fact that in *Bracco Diagnostics*, the Food and Drug Administration (“FDA”) had sent a number of warning letters to the defendant alerting them that their cited studies did not support the given marketing claims. *Bracco Diagnostics*, 627 F. Supp. 2d at 402 (“although not dispositive, the FDA agrees with the Court’s findings in numerous letters sent to GEH, including one as recent as March 21, 2005, where it states that the results of the NEPHRIC study cannot be extrapolated to CM other than Omnipaque in GEH advertising.”) There are no such damning facts here to support any allegation of misrepresentation.

Solsys also failed to address the well-settled case law cited by Organogenesis that holds “[c]ontext can often be important . . . and this is particularly true where, as here, the target of the advertising is . . . a more well informed and sophisticated audience” *Plough, Inc. v. Johnson & Johnson Baby Prods. Co.*, 532 F. Supp. 714, 717 (D. Del. 1982).⁶ No reasonable person (certainly no reasonable clinician, researcher, or wound care specialist) who would have received the Study in the journal, or Organogenesis’s Cover E-Mail that included and incorporated the full Study, could have been misled or deceived by its contents. A reader may disagree with certain methods or conclusions advanced in the Study, but that is hardly an example of the kind of consumer deception that the Lanham Act was designed to remedy. Rather, it is the essence of

⁶ See also *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229 (3d Cir. 1990) (“a target audience’s special knowledge of a class of products is highly relevant.”) and *Ameritox, Ltd. v. Millennium Labs, Inc.*, No. 8:11-cv-775-T-24-TBM, 2012 WL 33155, *3 (M.D. Fla. Jan. 6, 2012) (dismissing false advertising claim for failure to plead that advertisements actually deceived customers or had the tendency to deceive a substantial portion of the targeted audience). Even though Organogenesis cited and discussed these cases and their holdings, Solsys failed to address them — a telling admission that it has nothing to say on this point.

scientific debate that First Amendment jurisprudence teaches should be resolved in academic journals, and not in civil courtrooms.⁷

B. Solsys's Argumentative Attack on the Peer-Reviewed Study is Contrary to, and Unsupported by, the Complaint.

Solsys presents a lengthy straw man argument concerning “predatory journals” that lack editorial integrity and a robust peer-review process. It warns against the parade of horrors that might result if courts adopt a blanket rule to “immunize” statements about science and technology from liability under the Lanham Act if such statements are published in such a journal. *See* Opp’n at 10-11; 21-23. But Solsys’s Complaint nowhere alleges that *Advances in Wound Care*, an independent scientific publication of the WHS and an authoritative desktop reference for wound care professionals, is a “predatory journal” that lacks necessary editorial oversight over the peer-review process. Nor does Solsys anywhere allege that the journal was somehow “captured” by Organogenesis, or that the journal publishers otherwise engaged in a conspiracy with Organogenesis to publish a junk science article the purpose of which was to malign or disparage Solsys or its cadaver-based skin substitute product, TheraSkin.

Solsys’s attempt to argue this claim in a brief where the claim nowhere appears in the pleading is improper and borders on sanctionable. If Solsys has a good faith basis, consistent with Rule 11, to believe it can plead and prove such a case, it should plead it. And, were it to do so, it must also add as necessary parties the authors of the Peer-Reviewed Study, as well as the publisher and editorial board of the journal that published the article, as either joint tortfeasors or

⁷ Solsys further tries to muddy the clear waters of First Amendment and Lanham Act precedent in its treatment of *Semco, Inc. v. Amcast, Inc.*, 52 F.3d 108, 110-11 (6th Cir. 1995). The short answer is that *Semco* has nothing to do with peer-reviewed journals and the First Amendment. In *Semco*, the head of a company penned an article for a non-scientific trade publication where he made false claims about his company’s products. The company then distributed the trade publication article. *Id.* *Semco* is wholly inapposite.

aiders and abettors. Absent such additional factual allegations and necessary parties, however, Solsys's new arguments are completely unsupported by the operative Complaint and they should be wholly disregarded.

In any event, Solsys's concerns about the peer-review process are misguided and equally unsupported by the cases it cites. The requirements articulated in cases such as *ONY* and *Bracco Diagnostics* provide sufficient protection using methods of science. Thus, published research conclusions should have a basis in the scientific method, should rely on non-fraudulent data, and should not be misconstrued or misrepresented. These safeguards provide sufficient protection against misuse of otherwise protected First Amendment speech and provide the courts adequate flexibility to weed out cases where the debate is better done in the scientific, rather than the legal, realm. Any party who feels as though a scientific article impugns its product or its reputation has recourse to "methods of science." It may petition the journal's editorial board or its publisher to raise its concerns, and it has every opportunity to offer contrary opinions in the form of a letter to the editor or the submission of an alternative scientific study of its own. But "methods of litigation" challenging scientific studies that are published in respected journals and subject to the academic rigor of peer-review are barred by the First Amendment.

C. Solsys Has Not Sufficiently Pleaded That the Challenged Statements Actually Deceived or Had the Tendency to Deceive a Wound Care Specialist Audience.

Solsys's Complaint should also be dismissed because it failed to allege sufficient facts to make it plausible that any challenged statement in the Cover E-Mail "actually deceive[d] or has the tendency to deceive a substantial segment of its audience." *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 272 (4th Cir. 2002). Solsys has not pleaded facts to establish that Organogenesis disseminated any false or misleading statements of fact (as opposed to simply restating non-actionable statements of scientific opinion in an independently published and reviewed research

study with which Solsys disagrees). Moreover, there are no factual allegations that the Cover E-Mail (or the Peer-Reviewed Study incorporated in its entirety into the Cover E-Mail) deceived or had a tendency deceive a substantial segment of the intended audience of sophisticated health care professionals to which it was directed.

When evaluating this second point, “[c]ontext can often be important in discerning the message conveyed and this is particularly true where ... the target of the advertising is not the consuming public but a more well informed and sophisticated audience.” *Sandoz Pharms.*, 902 F.2d at 229 (quoting *Plough, Inc.*, 532 F. Supp. at 717). In an effort to avoid considering the higher sophistication of the medical and academic audience to which the article was directed, Solsys cites cases that dealt with whether non-professional consumers could plausibly be misled. *Genzyme*, for example, discussed how patients as the “ultimate consumer” of a pharmaceutical product could be misled. *See Genzyme Corp.*, 906 F. Supp. 2d at 17-18. The target audience for skin substitute wound treatments and medical devices, however, is undisputedly clinicians and wound care specialists, not their patients. Solsys could not plausibly allege that patients would purchase a skin substitute like they might a prescription drug. More importantly, however, it is legally impossible to deceive a sophisticated audience with any challenged statement in the Cover E-Mail because the actual Peer-Review Study that it summarized was fully incorporated into the Cover E-Mail itself for the reader to evaluate independently. Solsys cites no case where a similar advertisement was deemed actionable under the Lanham Act.

II. Solsys’s Demand for a “Retraction of Any References to or Any Information Regarding” the Study Is an Illegal Prior Restraint Under the First Amendment.

Solsys doubles down and admits that it seeks to compel Organogenesis to issue “*a retraction of any references to or any information regarding*” the Study. *See* Opp’n at 29-30 (emphasis in original). Prior restraint has long been condemned in the United States, and in

Virginia specifically. *See, e.g., Commonwealth v. Simone*, 63 Vir. Cir. 216, 2003 WL 22994238, at *4 (Va. Cir. Ct. 2003). When Justice Joseph Story described the scope of liberty of the press protected by the First Amendment, he condemned “previous restraints,” whether coming from a licensor or a judge: “the liberty of the press, as understood by all England, is the right to publish without any previous restraint, or license; so, that neither the courts of justice, nor other persons, are authorized to take notice of writings intended for the press; but are confined to those, which are printed.” 3 Joseph Story, *Commentaries on the Constitution of the United States* § 1879 (1833).⁸

Solsys asks this Court to stifle the academic contributions of the non-party authors of the Study, as well as the journal that published it, and seeks judicially to compel Organogenesis to retract and block its distribution of constitutionally-protected scientific opinions. Solsys cites no case (and Organogenesis is aware of no case) in which a federal or state court has enjoined the distribution of a peer-reviewed scientific study expressing scientific opinions and conclusions based on such peer-reviewed research. Indeed, this would be a bizarre result because the Supreme Court and federal courts have consistently held that academic freedom is “a special concern of the First Amendment” and subject to the highest legal protections. *See, e.g., Keyishian*, 385 U.S. at 603; *Offit*, 2010 WL 883745, at *4.

⁸ Free speech protections provided by the U.S. and Virginia Constitutions are co-extensive. “The plain language of the Virginia Constitution provides that the government shall not pass any law abridging the freedom of speech because free speech is a bulwark of liberty and can never be restrained, though citizens must be responsible for the abuse of such free speech. The plain language of these provisions appears to encompass expression of ideas, and the U.S. Supreme Court appears to have long read the freedom of speech guaranteed by the First Amendment to be speech about ideas.” *Simone*, 2003 WL 22994238, at *5.

CONCLUSION

Solsys's disagreement with the Peer-Reviewed Study should be resolved using methods of science, not litigation. No case law supports Solsys's claims here. The First Amendment compels dismissal of Solsys's unprecedented Complaint in its entirety and with prejudice.

Dated: May 30, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify on this 30th day of May, 2018, that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filings (NEF) and paper copies of the document will be sent to those indicated as non-registered participants.

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